

REMARKS

In the Office Action dated March 24, 2008, the Examiner rejected claims 1, 8-14, 29 and 33-35 under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,805,118 to Brooker (Brooker II). The Examiner also rejected claims 24-27 and 32 as being obvious over Brooker II, and claims 3-7, 28 and 30 as being obvious over Brooker II in view of USP 5,178,138 to Walstrom.

At the outset, Applicants note that, in an Office Action mailed three years ago on August 9, 2005, the Examiner rejected claims 1-3, 9 and 10 under 35 USC 102(b) as being anticipated by USP 6,269,810 to Brooker (Brooker I), and further rejected claims 4-8 and 24-27 as being obvious over Brooker I in view of one of U.S. Patent No. 6,390,091 to Banner, U.S. Patent No. 6,527,011 to Mantz, or U.S. Patent No. 6,581,600 to Bird. Notably, the Examiner indicated that claims 11-14 were allowable over Brooker I.

In response, Applicants filed an Amendment and Reply on November 29, 2005 (mailed November 15, 2005), wherein Applicants rebutted the rejections. Subsequently, the Examiner *agreed* that the rejections were overcome, and issued another Office Action allowing certain claims (11-14), objecting to another claim (10) and rejecting the remaining claims over a *new* reference (February 8, 2006 Office Action). Following that Office Action, three (3) additional Office Actions (August 9, 2006, February 8, 2007, September 11, 2007) were mailed wherein Brooker I was not mentioned or referred to by the Examiner. Now, after four intervening Office Actions and subsequent responses, the Examiner has reverted back to essentially the *same reference* as cited the August 9, 2005 Office Action with respect to claims 1 and 24. More troubling is that the Examiner has now further indicated that claim 11 (previously indicated as being allowed over Brooker I) stands rejected over Brooker II. In this regard, Applicants note that Brooker I and II are directly related and have an *identical specification/disclosure*.

As set forth in the MPEP, “piecemeal examination should be avoided as much as possible,” and the “examiner ordinarily should reject each claim on all valid

grounds available” (MPEP 707.07(g)). In this case, Applicants previously overcame rejections with respect to Brooker I, and the Examiner even indicated that certain claims were allowable thereover. Now, three years and four office actions/responses later, Applicants are essentially back to where they started. Applicants submit that the Examiner got it right the first time, and that the rejections over Brooker (I or II) should be withdrawn again for at least the reasons set forth previously and as further stated below.

Remarks About The Prior Art Rejections:

Claims 1, 3-10, 24-29, 30 and 32-35:

Independent claims 1 and 3 each recite “a second inhalation conduit communicating with said input end of said chamber housing, wherein said one-way inhalation valve is located in said second inhalation conduit, said second inhalation conduit comprising *an oxygen intake line communicating with said one-way inhalation valve.*” In addition, independent claim 24 recites “*transmitting oxygen from a gas source* through a holding chamber and an inhalation conduit to the patient during an inhalation sequence of a breathing cycle.”

As previously admitted by the Examiner, Brooker does not disclose “providing oxygen as [a] gas source” (August 9, 2005 Office Action at 6). Applicants submit that the Examiner was correct, and that the Examiner’s rejections should be withdrawn on this basis alone.

In the most recent Office Action, the Examiner now asserts that “the second inhalation conduit [comprises] an oxygen intake line communicating with the one way inhalation valve,” referring to FIG. 4 and connectors 14 and 15 of Brooker II. Applicants respectfully disagree. As shown in FIGS. 2 and 4 of Brooker II, *ambient air* passes directly through inlet 13a through the filter 13 and connectors 14 and 15 and into the inhalation conduit by way of fitting 17 (Col. 4 lines 32-54) – there is no oxygen intake line communicating with a valve. Accordingly, the Examiner’s rejection of claims 1 and 33 over Brooker under 35 USC 102(b) has been overcome

and notice to that effect is earnestly solicited.

Applicants further submit that it would not have been obvious to modify the invention of Brooker by providing an oxygen intake line. Indeed, Brooker repeatedly and expressly teaches *against* any such combination. In particular, Brooker expressly discloses:

It is an *object* of the present invention to provide a pulmonary dosing system for supplying to a patient *capable of normal breathing* a predetermined amount of respirable therapeutically active material (Col. 2, lines 6-9) (emphasis added).

Containment box 7 also has an *ambient air inlet port* and filter in conjunction with a nebulizer and a plenum chamber to provide the inhalation line 4 and mouthpiece 5 with *ambient air* (Col. 4, lines 11-14) (emphasis added).

It will be remembered that the pulmonary dosing system of the present invention *does not include a respirator or the like, and is intended for use with patients who can breath normally* (Col. 4, lines 30-35) (emphasis added).

In sum, because Brooker II does not disclose the claim recitations, and further teaches against any modification, the Examiner's rejections should again be withdrawn, as they were in the August 8, 2006 Office Action.

With respect to claim 3, Applicants further note that the Examiner has cited Walstrom only for the proposition of providing a pressurized metered dose inhaler within the second conduit *downstream* of the of the one-way inhalation valve and *upstream* of the interior space of the chamber housing (August 8, 2006 Office Action at 8, citing Walstrom at FIGS. 6 and 11)). Applicants note that the embodiment of FIG. 11 is directed to a nebulizer, not a PMDI (Walstrom at Col. 8, lines 55-62). Accordingly, the Examiner's rejection of claim 3, and claims 4-7, 28 and 30 depending therefrom, should be withdrawn for at least this additional reason.

Applicants further note that Walstrom does not disclose that the embodiments incorporating the extensions 70 and 71 are used with the ventilator, but rather are used with spontaneously breathing patients who inhale to draw air through the device

(Walstrom at Col. 7, line 35 to Col. 8, line 34). For at least this additional reason, Applicants respectfully submit that the Examiner's rejection of claim 3, and claims 4-7, 28 and 30 depending therefrom, should be withdrawn.

In addition, as shown in FIGS. 2 and 4 of Brooker II, ambient air passes directly through inlet 13a through the filter 13 and into the inhalation conduit by way of fitting 17 (Col. 4 lines 32-54). In contrast, the ventilator of Walstrom includes a closed inhalation conduit 21, 23 that is connected with the ventilator 20 (Walstrom at FIGS. 1 and 2, Col. 4, lines 29-43). As such, there is absolutely no suggestion to combine the references. Indeed, any such combination would render both devices inoperative for their intended, express purposes (MPEP 2143.01), and would change the principle of operation of Brooker (MPEP 2143.01). Accordingly, claims 3-7, 28 and 30 should be passed to allowance for at least this additional reason.

Claims 11-14:

As noted above, the Examiner previously indicated that claims 11-14 were allowable over Brooker I, and correctly so. In particular, neither Brooker I nor II discloses or suggests that "said first portion [of an adaptor] defines a first passageway having a first and second channel and wherein said second portion comprises a second passageway, and wherein said adapter further defines a third passageway communicating between said first passageway and second passageways, wherein said one-way exhaust valve is disposed in said second passageway." Specifically, Brooker II does not disclose or suggest that a first leg 3a of adapter 3 has or defines a passageway having "a first and second channel" or a "third" passageway communicating between the legs 3a and 3b. Accordingly, the Examiner's rejections should be withdrawn and notice to that effect is earnestly solicited.

Remarks About Second and Third Supplemental Information Disclosure Statements:

As noted in Applicants remarks submitted in the Amendment and Reply filed

mailed December 11, 2007, Applicants have not received an initialed Form PTO-1449 acknowledging that the Examiner considered the timely filed Second Supplemental Information Disclosure Statement. Likewise, Applicants have not received an initialed Form PTO-1449 filed February 8, 2008 with a timely filed Third Supplemental Information Disclosure Statement. Applicants respectfully request that the Examiner review the Second and Third Supplemental Information Disclosure Statements, along with the references cited therein, and initial the Form PTO-1449's to indicate his consideration thereof.

CONCLUSION:

If for any reason this application is not considered to be in condition for allowance and an interview would be helpful to resolve any remaining issues, the Examiner is respectfully requested to call the undersigned attorney at (312) 321-4713.

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